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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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7590

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EXAMINER

CRIARES, THEODORE J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/586,747

Applicant(s)

BURNETT ET AL.

Examiner

Theodore J. Criares

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6, 8-10 and 12-14 is/are allowed.
- 6) ☒ Claim(s) 7, 11 and 15-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **CLAIMS 1-33 ARE PRESENTED FOR EXAMINATION**

Applicants' arguments filed January 18, 2002 have been fully considered but they are not persuasive.

Applicants argue that the phrase "conformationally native subunit of chronic intracellular pathogens which in the course of natural infection with that pathogen is exposed to the host immune system on the surface of free pathogen and/or pathogen-infected cells" e.g. HIV virus is not disclosed in the prior art since the specific language is not taught in the Tice et al. reference. It is also argued that Tice et al. only teaches generically that antigens can be encapsulated in the micro-spheres taught therein. However, the claims are to be interpreted in their broadest meaning. There is a lack of teaching in applicant's specification what the phrase means and was not previously identified as a critical part of applicants' invention. The rejection under 35-U.S.C. 103(a) as set forth in the Office Action of October 4, 2001 is maintained and deemed proper.

Applicants' invention which issued as U.S. Patent 5,762,965 was deemed to be the size of the molecule of the PLGA micro-sphere.

Applicants' argument that claims 7, 11 and 16 inserting the term "comprising" in lieu of "consisting" is not persuasive since the former term broadens the composition which is claimed, i.e., that additional types of micro-spheres are included in the composition which are not supported in the specification.

Claims 1-6, 8-10, 12 -14 are allowed.

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Claims 7 and 11 would be allowed if the tem "comprising" is deleted from these claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

In view of applicants' argument that the subunit is not taught by Tice et al. since the term "antigen" is generic and that the micro-spheres of the Tice et al. encapsulate hormones rather than antigens the following new rejection is deemed proper.

Claims 15-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cleland et al. (WO 95/11010).

Cleland et al. teach at the abstract, page 1, lines 16-32, page 8, line 8 to page 19, line 30 compositions of PLGA microspheres with HIV adhereing thereto. The difference between applicants' claims and the Cleland et al. teaching is that the specific language as set forth in applicants' claims is not within the cited referenced patent. However, the skilled artisan would have been motivated to form applicants' claimed compositions since at page 10, line 13 to page 15, line 20 general methods of formulating compositions of PLGA micro-spheres encapsulating HIV are taught. Applicants' claims 15-19 and 24-33 to compositions of subunits, i.e., HIV virus adhering to, encapsulated, formed by evaporation or extraction, ratio of lactide to glycolide etc., as set forth in these claims, are within the teachings of of the cited pages of the Cleland reference.

Claims 20-23 are rejected since they depend from rejected claim 15.

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The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 18 USPQ 2d 1885, (Fed. Cir. 1991). In view of the above rejection it is deemed that the evidence presented has established a prima facie case of obviousness is presented.

In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed, but can be deferred until allowability is indicated..

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

"Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

Claims 1-6, 8-10 and 12 -14 are allowed.


Claims 7, 11 and 15-33 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is 308-4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moeizie can be reached on 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-6897 for regular communications and N/A for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.



Theodore J. Criares  
Primary Examiner  
Art Unit 1617

T.J. C  
July 22, 2002